



September 24, 2019

Seema Verma, MPH, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
CMS-1715-P, Room 445-G
Hubert Humphrey Building
200 Independence Ave, SW
Washington, DC 20201

Submitted electronically

Re: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals-Within-Hospitals

Dear Secretary Verma:

On behalf of the American Society for Clinical Pathology, I am writing to provide comment on the [CY 2020 Outpatient Prospective Payment System \(OPPS\) Notice of Proposed Rulemaking \(NPRM\)](#). Specifically, I am writing in regards to the Proposed Rule's provisions concerning Price and Quality Transparency and the Laboratory Date of Service policy.

The ASCP is a 501(c)(3) nonprofit medical specialty society representing more than 100,000 members. Our members are board certified pathologists, other physicians, clinical scientists (PhDs), certified medical laboratory scientists/technologists and technicians, and educators. ASCP is one of the nation's largest medical specialty societies and is the world's largest organization representing the field of pathology and laboratory medicine. As the leading provider of continuing education for pathologists and medical laboratory personnel, ASCP enhances the quality of the profession through comprehensive educational programs, publications, and self-assessment materials.

I. Changing the test results requirement at 42 C.F.R. § 414.510(b)(5)(iv)

In its proposed OPPS NPRM, CMS outlines three possible changes to its current policy of exempting molecular pathology tests and Advanced Diagnostic Laboratory Services (ADLTs) from its laboratory date of service policy. The proposed alternatives on which CMS is seeking comment are as follows:

- **Changing the Test Results Requirement** to mandate that the ordering physician determine whether the results of the molecular pathology test or ADLT are intended to guide treatment during a hospital outpatient encounter.
- **Limiting the exemption for molecular pathology services** to only those that are advanced Diagnostic Laboratory Tests
- **Blocking blood banks and centers from the ability to directly bill** for molecular pathology services directly tied to an outpatient encounter.

ASCP's comments on these proposals follows.

A. Changing the Test Results Requirement at 42 CFR 414.510(b)(5)(iv)

ASCP is concerned with CMS's proposal to require the ordering physician to determine whether the molecular pathology or ADLT is intended to guide treatment during a current or future hospital outpatient encounter. This proposal would increase operational challenges in billing for these services. As CMS is aware, hospitals "are having difficulty developing the systems changes necessary to provide the performing laboratory with the patient's hospital outpatient status, beneficiary demographic information, and insurance information, such as whether the beneficiary is enrolled in original fee-for-service Medicare or a specific Medicare Advantage plan." Requiring hospitals to convey additional information will increase the current difficulties that clinical laboratories encounter in trying to secure from hospitals the information necessary to bill directly for their services.

CMS notes in its proposed rule, that a number of factors could influence a test's relevance to a hospital outpatient encounter. These include the beneficiary's current diagnosis or lack thereof, the procedures that the beneficiary may have, and the beneficiary's current and previous medical history. If the patient does not yet have a diagnosis, or if the physician is not familiar with the beneficiary's medical history, the physician may not be able to determine whether the test would guide an outpatient treatment or not. As a result, we anticipate that these determinations will lead to an inconsistent and frustrating application of the rule. Moreover, this requirement would impose a significant burden for hospitals to train ordering physicians on their obligation to determine whether a molecular pathology test or ADLT guides hospital treatment, either now or in the future.

In addition, the hospital would need to ensure that ordering physicians actually make a determination for each molecular pathology test and ADLT that is subject to the date of service rule, per 42 C.F.R. § 414.510(b)(5). It should be noted that such a determination is unique to molecular pathology and ADLT services since ordering physicians would generally not have to make such a determination for other tests. The systems changes that would be needed must be sufficient to ensure that hospitals do not inadvertently bill for a service that is unrelated to hospital outpatient care.

Furthermore, this policy seems in conflict with the Agency's "Patients Over Paperwork" initiative, which aims to reduce the regulatory and paperwork burdens on physicians so they can focus more on providing high-quality care that improves patient health.

Due to the challenges this policy presents, ASCP urges CMS not to adopt this proposal.

B. Limiting the Laboratory DOS Exception at 42 CFR 414.510(b)(5) to ADLTs

In our comments on the CY 2018 OPPTS proposed rule, ASCP urged CMS to exclude molecular pathology services and multiple analyte algorithmic assays as well as ADLTs from the DOS policy. Many of the issues that apply to ADLTs also apply when two laboratories offer a molecular pathology or MAAAs, rather than only a single laboratory.

While an ADLT may be offered at a single laboratory, molecular pathology tests and MAAAs are also highly specialized tests that may face similar supply/access issues. We note that there are a number of FDA-approved devices approved for specific molecular pathology services, but that vast majority of molecular pathology services are Laboratory Developed Tests (LDTs), performed by the laboratories that developed and validated them. Because LDTs are specific to the developing laboratory, the coverage policy for these services was most likely issued by the MAC with jurisdiction for the laboratory's location. We are concerned that not allowing laboratories to bill directly for these services could take away the incentive for clinical laboratories to develop innovative diagnostics, which directly benefits quality patient care. Moreover, we do not believe that the existence of a few FDA-approved test kits for molecular pathology services should be the driver for how CMS should handle *all* molecular pathology services.

ASCP opposes adoption of this policy option.

C. Excluding Blood Banks and Blood Centers from the Laboratory DOS Exception at 42 C.F.R. § 414.510(b)(5)

CMS states in its NPRM that it believes "that molecular pathology testing, when performed by blood banks or centers, is inherently tied to a hospital service because hospitals receive payment for and/or use the blood and/or blood products provided by blood banks and blood centers to treat patients in the hospital setting. Accordingly, we believe that such testing is so connected to the treatment furnished to the patient in the hospital that it must be considered a hospital service and that hospitals should be permitted to bill and receive payment for such testing performed on these blood and/or blood related products."

ASCP concurs that many of the molecular pathology services performed by blood banks and blood centers are hospital services and that these services should be billed by the hospital. Accordingly, ASCP supports the Agency's proposal to exclude blood banks and blood centers from the laboratory DOS policy, such that the DOS for laboratory testing performed by blood banks and centers on specimens collected from a hospital outpatient during a hospital outpatient encounter would be the date of specimen collection provided the testing is performed for *blood compatibility testing purposes*.

II. Proposed Requirements for Hospitals to Make Public a List of Their Standard Charges

On June 24, the President signed Executive Order (EO) 13877, [Improving Price and Quality Transparency in American Healthcare to Put Patients First](#). The EO makes it the policy of the Federal Government to increase the availability of meaningful price and quality information for patients. In addition, it directs

the Secretary of the U.S. Department of Health and Human Services to adopt regulations to require hospitals to publicly post standard charge information.

As a result, CMS is proposing in the [CY 2020 OPSS NPRM](#) to require hospitals to make public their standard charges available online in a machine-readable format starting in 2019. Section 2718(e) requires each hospital operating within the United States to establish (and update) and make public a yearly list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups established under section 1886(d)(4) of the Social Security Act.

A. Proposal to Define Hospital Items and Services

As part of the NPRM, CMS proposes to define hospital "items and services" to include all items and services (including individual items and services and service packages) provided by a hospital to a patient in connection with an inpatient admission or an outpatient department visit for which the hospital has established a charge. Examples include: Supplies, procedures, room and board, use of the facility and other items (generally described as facilities fees), services of employed practitioners (generally described as professional charges), and any other items or services for which the hospital has established a charge. While not specifically identified among these items, clinical laboratory services are clearly included. We support including clinical laboratory services as one of the covered "items and services."

B. Proposal to Define Standard Charges

In addition, CMS also defines what sort of pricing information must be provided. Here the Agency proposes to define "standard charges" to mean the hospital's gross charge and *payer-specific negotiated charge* (emphasis added) for an item or service. The Agency elaborates that hospitals would be required to make their standard charges public in two ways:

- 1) Machine-readable file posted online containing all hospital standard charge information (both gross charges and payer-specific negotiated charges) for all items and services provided by the hospital.
- 2) Consumer-friendly format that displays and packages payer-specific negotiated charges for a limited set of 'shoppable' services.

C. Civil Monetary Fines

CMS proposes that it "may" impose a civil monetary penalty (CMP) "upon a hospital for a violation of each requirement of proposed 45 CFR part 180." However, it states at 84 FR 39592 that "[t]he maximum daily dollar amount for a CMP to which a hospital may be subject would be \$300. We are proposing that even if a hospital is in violation of multiple discrete requirements of proposed 45 CFR part 180, the maximum total sum that a single hospital may be assessed per day is \$300." CMS further states that it "believe[s] this proposed CMP amount strikes a balance between penalties that are sufficiently harsh to incentivize compliance but not so severe as to be punitive.

D. Comment

Overall, ASCP supports the Agency's proposal to improve price and quality transparency as well as the proposals to include negotiated charge data along with a hospital's gross charges. In theory, this requirement could encourage competition among hospitals and, hopefully, will improve quality and reduce cost. Information is power and giving patients access to cost data for their laboratory tests empowers those willing to be actively involved in the management of their healthcare. That said, one potential concern is that many payers prohibit providers from disclosing information on negotiated rates. As a result, CMS needs to recognize that this issue must be dealt with in a manner that minimizes potential disruptions in the marketplace for healthcare services and insurance coverage.

ASCP believes that the EO and the Agency's proposal raise interesting policy options that CMS should consider in future rulemaking. Under Section 216 of the Protecting Access to Medicare Act (2016), CMS was required to develop a new Medicare Clinical Laboratory Fee Schedule (CLFS). PAMA required applicable clinical laboratories to provide to CMS data on negotiated payment rate and associated test volume data received from private payers. Unfortunately, when CMS crafted its regulations to implement these requirements, its regulations largely ignored hospital clinical laboratories data from the Agency's calculation of median payment rates. As a result, the data used by CMS fails to reflect the overall "market rate" prices specified by Congress.

Given that the proposals outlined here require hospitals to report private payer payment rates on clinical laboratory services, ASCP believes that CMS needs to take the next step with this proposal and secure price *and associated volume* data for clinical laboratory testing furnished to hospital patients. This will better ensure the CLFS prices it calculates reflect the true market prices. With CMS's data collection methodology being a central issue of concern in the lawsuit, *American Clinical Laboratory Association vs. Azar*, the OPPI transparency initiative may provide the Agency the most practical regulatory mechanism to match its data collection methodology with Congress's expectations. Accordingly, ASCP also encourages CMS to ensure that the clinical laboratory pricing information required to be provided by hospitals as part of this transparency initiative is consistent with the type of data required by Section 216 of the Protecting Access to Medicare Act (PAMA) to minimize duplicative and/or excessive regulatory burden.

With regard to civil monetary penalties, ASCP notes that PAMA [See [42 CFR 414.504\(e\)](#)] specifies civil monetary penalties for laboratories that do not report data as required. PAMA authorizes the Secretary to "apply a civil money penalty in an amount of *up to \$10,000 per day for each failure to report or each such misrepresentation or omission*. Given that it is well known that compliance with PAMA's data submission requirements were below expectations, we find it unlikely that CMS's proposed maximum daily CMP of \$300 will be sufficient to encourage prompt reporting of pricing data by hospitals.

Another point on which ASCP seeks to comment on concerns the impact, if any, this proposal will have on surprise billing. It is unclear to us that the transparency proposals will have a significant impact on the *frequency* with which surprise billing occurs; hopefully, however, the proposal may benefit patients in that the *amount* that they are ultimately charged, per provider encounter, may be less. Ultimately, the issue of surprise billing is largely fueled by payers providing inferior payment rates, which prompts

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providers, including specialists, to decline in-network participation. This creates network adequacy issues that increase the frequency of patients receiving unanticipated medical bills.

ASCP appreciates the opportunity to comment on this proposed rule. If ASCP can be of any assistance, please contact me or Matthew Schulze, ASCP's Director of Public Policy at 202-735-2285 or by email at matthew.schulze@ascp.org.

Sincerely,

A handwritten signature in blue ink that reads "Gene P. Siegal". The signature is written in a cursive style with a large initial "G" and "S".

Gene Siegal, MD, PhD, FASCP

President, ASCP